

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN
GREEN BAY DIVISION

ANNIKEN PROSSER,

Plaintiff,

Case No. 20-cv-194

v.

ALEX AZAR, in his capacity as Secretary
of the United States Department of Health
and Human Services,

Defendant.

MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY
JUDGMENT BASED ON PLAINTIFF'S LACK OF STANDING

I. Introduction

As the prior briefing in this case has established, regardless of the outcome of her case, Ms. Prosser will not be required to pay out-of-pocket for the denied claims at issue (see ECF 13, at p. 8 and *infra*, at p. 5), and any assertion that she will be liable for future treatment is speculative. She therefore lacks Article III standing because a ruling in Ms. Prosser's favor will not redress any actual financial injury to her. Under similar circumstances, courts in the Central District of California dismissed for lack of standing two cases involving Novocure's tumor treatment field therapy where the beneficiary is not financially liable. *See Komatsu v. Azar*, No. 8:20-cv-00280 (C.D. Cal. Sept. 24, 2020) (decision attached); *Pehoviack v. Azar*, No. 8:20-cv-00661, 2020 WL 4810961 (C.D. Cal. July 22, 2020) (decision attached). For the reasons set forth in those decisions and below, summary judgment should be granted in the defendant's favor because Ms. Prosser lack standing to pursue this action.

II. Statutory and Regulatory Background

A. “Reasonable and Necessary” Medicare Expenses

This case centers on Medicare coverage for tumor treatment field therapy (TTFT) over four months in 2018 for Ms. Prosser’s glioblastoma multiforme (GBM), an incurable form of brain cancer. AR 4310–15. TTFT, or Optune, uses electric fields to prevent tumor growth and is manufactured by Novocure. AR 303. Novocure rents the TTFT device to beneficiaries on a monthly basis. AR 189.

Medicare is a federal health insurance program for the aged and disabled. *See* 42 U.S.C. § 1395 *et seq.* For a medical service to be covered by Medicare, it must fit within a benefit category established by the Medicare statute and regulations. 42 U.S.C. § 1395k; 42 C.F.R. part 410. Furthermore, “no payment may be made under . . . part B for any expenses incurred for items or services[] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” 42 U.S.C. § 1395y(a)(1)(A). The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program for the Secretary, has historically interpreted “reasonable and necessary” to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental, in order to qualify for reimbursement. *See* Medicare Program Integrity Manual (MPIM) § 13.5.4.¹

¹ The MPIM is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf>. The MPIM “is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment.” *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

To administer the “reasonable and necessary” standard, the Secretary employs a range of tools, from formal regulations to informal manuals. In choosing among these options, the Secretary is not required to promulgate regulations or policies that, “either by default rule or by specification, address every conceivable question” that may arise. *Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 96 (1995). The Secretary may articulate “reasonable and necessary” standards through formal regulations that have the force and effect of law throughout the administrative process. *See* 42 U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also issue National Coverage Determinations (NCDs) “with respect to whether or not a particular item or service is covered nationally.” 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060.

The Secretary has delegated to CMS broad authority to determine whether Medicare covers particular medical services. *See* 42 U.S.C. §§ 1395y(a), 1395ff(a), (f). CMS, in turn, contracts with Medicare Administrative Contractors (MACs), such as CGS Administrators in this case, to administer certain day-to-day functions of the Medicare program. 42 U.S.C. § 1395kk-1. Consistent with controlling regulations and NCDs, a MAC makes coverage determinations, issues payments, and develops Local Coverage Determinations (LCDs) for the geographic area it serves, *see* 42 U.S.C. § 1395ff(f)(2)(B), in accordance with the reasonable and necessary provisions in 42 U.S.C. § 1395y(a)(1). *See* 42 U.S.C. §§ 1395kk-1(a)(4). An LCD is binding only on the contractor that issued it, and only at the initial stages of the Medicare claim review process, as opposed to later stages, if a claimant should appeal a determination by a MAC. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II).

In August 2014, the MACs issued the original LCD for TTFT, determining that based on the evidence available at the time, TTFT was not a “reasonable and necessary treatment.” AR 133. The LCD was revised, effective September 1, 2019, to permit coverage for newly diagnosed GBM

and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances.²

B. Administrative Review Process

To ensure efficiency and economy, Congress has required that a multi-level administrative claims and appeals process be exhausted before a Medicare beneficiary may seek judicial review. 42 U.S.C. § 1395ff; *see also Heckler v. Ringer*, 466 U.S. 602, 627 (1984). As the statutory and regulatory framework establishes, a Medicare beneficiary or supplier who seeks to challenge a denial of coverage must first request a redetermination of the denial by a Medicare contractor.³ 42 U.S.C. § 1395ff(a)(3)(B)(i); 42 C.F.R. §§ 405.904(a)(2), 405.948. Next, the beneficiary may request reconsideration by a qualified independent contractor (QIC). 42 U.S.C. §§ 1395ff(c)(1), (2); 42 C.F.R. § 405.960. The QIC's panel members must have "sufficient medical, legal, and other expertise, including knowledge of the Medicare program." 42 C.F.R. § 405.968(c)(1); *see* 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. § 405.960. An LCD is not binding at this and at higher levels of appeal. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b). After reconsideration, the beneficiary may request a hearing before an administrative law judge (ALJ). *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1002. Last, the beneficiary may request that the Medicare Appeals Council, a division of the Departmental Appeals Board of the U.S. Department of Health and Human Services, review the ALJ's decision. 42 C.F.R. § 405.1100. The MAC's decision represents the final decision of the Secretary. 42 C.F.R. § 405.1130. After a beneficiary

² The 2019 LCD is available at: <https://www.cms.gov/medicare-coverage-database/details/lcddetails.aspx?LCDId=34823&ver=27&DocID=L34823&bc=gAAAAIAAAAA&> (last visited Sept. 23, 2020).

³ A provider or supplier may also avail itself of the same appeals process if it accepts assignment of the claim from the beneficiary. 42 U.S.C. § 1395ff(b)(1)(C).

exhausts her administrative remedies, she can seek judicial review in federal court. *See* 42 U.S.C. § 1395ff(b)(1)(A)(i) (right to judicial review incorporating the review provisions of 42 U.S.C. § 405(g)).

C. Advanced Beneficiary Notice

If Medicare coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). However, the supplier is expected to be familiar with Medicare laws, regulations, and policies. 42 C.F.R. § 411.406. If the supplier should reasonably have known a claim would not be covered, Medicare is not responsible and the supplier must bear the loss of non-payment. 42 C.F.R. § 411.400(a). 42 C.F.R. § 411.404(b); *see* 42 U.S.C. § 1395pp. A provider may attempt to transfer liability for non-coverage and bill a Medicare beneficiary only by first obtaining the beneficiary's signature on an Advance Beneficiary Notice of Non-coverage form. If such notice is not given, "providers may not shift financial liability to beneficiaries." Medicare Claims Processing Manual, Ch. 30, § 50.2.1; *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 997–98 (9th Cir. 2012) (explaining that a valid Advance Beneficiary Notice is required "for the supplier to shift liability to the beneficiary"); *Almy v. Sebelius*, 679 F.3d 297, 311 n. 4 (4th Cir. 2012) (same).

As the ALJ found in the decision on review, because Novocure did not require Ms. Prosser to sign an Advance Beneficiary Notice, no matter the outcome of this case, she will not be financially responsible for the TTFT claims at issue. AR 4314. Ms. Prosser has not put forward evidence or alleged that Novocure has required her to sign an Advance Beneficiary Notice.

III. Factual and Procedural Background

Ms. Prosser was diagnosed with GBM in February 2016 and, after surgery, began TTFT in June 2016. AR 5392–93. CGS Administrators, the relevant MAC, denied coverage for claims for TTFT dated January 16, 2018, February 16, 2018, March 16, 2018, and April 16, 2018. AR 4310, 5138–41. CGS affirmed the denial on redetermination and found Novocure liable for the cost. AR 5130–32. The QIC upheld this decision on appeal. AR 5367–71. The ALJ at the next stage of review also upheld the denial of coverage and found that Novocure, not Ms. Prosser, would be liable for the cost. AR 4310–15. Ms. Prosser appealed to the Medicare Appeals Council and then escalated review to the district court after the Council could not issue a decision within the regulatory time frame. AR 4232.

Ms. Prosser filed her complaint in this court on February 7, 2020, alleging primarily that collateral estoppel precluded the Secretary from denying her claims since a previous ALJ decision granted coverage. After cross-motions for summary judgment, this court agreed with the Secretary that collateral estoppel is not available. Ms. Prosser subsequently filed a motion for reconsideration and, alternatively, certification of an interlocutory appeal pursuant to 28 U.S.C. § 1292(b). On September 24, 2020, the court denied her motion.

IV. Standard of Review

Summary judgment is appropriate where “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). In evaluating motions for summary judgment, all facts, and reasonable inferences drawn from those facts, are construed in the light most favorable to the nonmoving party. *See Hackett v. City of South Bend*, 956 F.3d 504, 507 (7th Cir. 2020) (citations omitted). However, where the nonmoving party would bear the burden of proof at trial, that party retains its burden of producing evidence that would

support a reasonable jury verdict. *See McCann v. Badger Mining Corp.*, 965 F.3d 578, 592 (7th Cir. 2020)

“Plaintiffs always bear the burden of showing they have standing to sue.” *Hummel v. St. Joseph Cty. Bd. of Comm’rs*, 817 F.3d 1010, 1016 (7th Cir. 2016) (citing *Lujan v. Def. of Wildlife*, 504 U.S. 555, 561 (1992)). When the issue of standing is raised in a motion for summary judgment, Plaintiffs “must offer evidence to support standing” and cannot rely solely on allegations. *Id.*; *see also Gwaltney of Smithfield v. Chesapeake Bay Found.*, 484 U.S. 49, 65–66 (1987).

V. Argument

Because Ms. Prosser is not liable for the denied claims, she has not suffered any concrete injury sufficient to confer Article III standing. The jurisdiction of federal courts is limited to hearing only cases and controversies. U.S. Const. art. III, § 2, cl. 1; *see Raines v. Byrd*, 521 U.S. 811, 818 (1997). An element of the case-and-controversy requirement is that the Plaintiff must have standing to sue. *Raines*, 521 U.S. at 818; *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 408 (2013). To establish standing, the Plaintiff must show she has “(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 136 S.Ct. 1540, 1547 (2016) (citations omitted). Ms. Prosser cannot meet any of these elements.

A. Plaintiff Has Not Suffered an Injury in Fact

Injury in fact is established by showing that the Plaintiff “suffered an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural or hypothetical.” *Spokeo*, 136 S.Ct. at 1548 (internal quotations omitted). Whether it is a “tangible” or “intangible” harm, a “concrete” injury “must actually exist,” in the sense it is “real” and “not

abstract”. *Id.* at 1548–50; *see also Groshek v. Time Warner Cable*, 865 F.3d 884, 886 (7th Cir. 2017).

1. Plaintiff has suffered no concrete injury

Ms. Prosser has suffered no concrete injury because she is not financially liable for the claims at issue in this case. The Supreme Court considered a similar issue a few months ago in *Thole v. U.S. Bank*, 140 S.Ct. 1615, 1619 (2020). Plaintiffs sued U.S. Bank under the Employee Retirement Income Security Act of 1974 (ERISA) alleging mismanagement of their defined-benefit retirement plan. *Id.* Because it was a defined-benefit plan, plaintiffs received a fixed payment each month regardless of fluctuations in the value of the plan. *Id.* The Court held that plaintiffs had no concrete stake in the lawsuit because “the outcome of this suit would not affect their future benefit payments.” The Court explained that if plaintiffs “were to *lose* this lawsuit, they would still receive the exact same monthly benefits that they are already slated to receive, not a penny less. If [plaintiffs] were to *win* this lawsuit, they would still receive the exact same monthly benefits that they are already slated to receive, not a penny more.” *Id.* (emphasis in original). The same is true in this case, if Ms. Prosser prevails, the Secretary will not pay her anything. If she loses, she will not owe the Secretary or Novocure anything.

Ms. Prosser further cannot rely on the provisions of the Medicare Act to allege injury and confer jurisdiction. The *Spokeo* Court explains:

Congress’ role in identifying and elevating intangible harms does not mean that a plaintiff automatically satisfies the injury-in-fact requirement whenever a statute grants a person a statutory right and purports to authorize that person to sue to vindicate that right. Article III standing requires a concrete injury even in the context of a statutory violation. For that reason, [plaintiff] could not, for example, allege a bare procedural violation, divorced from any concrete harm, and satisfy the injury-in-fact requirement of Article III.

Id. at 1549; *see also Meyers v. Nicolet Rest. of De Pere*, 843 F.3d 724, 727 (7th Cir. 2016)

(“Congress’ judgment that there should be a legal remedy for the violation of a statute does not mean each statutory violation creates an Article III injury.”); *Collier v. SP Plus Corp.*, 889 F.3d 894 (7th Cir. 2018) (finding no standing where no allegation of concrete harm beyond a statutory violation); *Casillas v. Madison Ave. Assoc.*, 926 F.3d 329 (7th Cir. 2019) (same).

Ms. Prosser’s allegation that the ALJ decision was not supported by substantial evidence amounts to a bare procedural violation that is “divorced from any concrete harm.” *Spokeo*, 136 S.Ct. at 1549; *see also Cal. Clinical Lab. Ass’n v. Sec’y of HHS*, 104 F. Supp. 3d 66, 78–79 (D.D.C. 2015) (finding another provision of the Medicare Act that allows for judicial review could not confer Article III standing). In *Spokeo*, the Court provided examples of the type of procedural violations that could constitute injury in fact, such as the inability to obtain public information used for voting, or failure to obtain information subject to disclosure under federal law. *Id.* Unlike those cases, however, any purported flaw in the ALJ’s reasoning did not cause Ms. Prosser to suffer the actual harm necessary for Article III standing. *See Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) (explaining that “deprivation of a procedural right without some concrete interest that is affected by the deprivation . . . is insufficient to create Article III standing.”). Therefore this suit should be dismissed for lack of standing.

2. Plaintiff cannot rely on conjectural or hypothetical harm

To the extent that Ms. Prosser relies on an assertion that her injury is the potential denial of future Medicare claims for TTFT, which is why she invoked collateral estoppel, that harm is too speculative and not imminent. In order to be an injury in fact, “a threatened injury must be certainly impending to constitute injury in fact, and . . . allegations of possible future injury are not sufficient.” *Amnesty Int’l*, 568 U.S. at 409 (internal quotation and citation omitted). Future denials of Medicare claims for TTFT is purely speculative. It assumes Ms. Prosser will continue to be

prescribed TTFT, that Medicare coverage will be denied⁴ (which is unclear given the 2019 changes to the LCD), and that she will be liable for payment if denied, which would further require that Novocure require Ms. Prosser to sign an Advance Beneficiary Notice before being provided treatment (which she has not alleged or shown). These are all speculative assumptions that do not establish standing. *See Bria Health Servs. v. Eagleson*, 950 F.3d 378, 386 (7th Cir. 2020) (finding residents of nursing home did not have standing to sue where plaintiffs alleged risk that residents would be discharged because this represented a “possible future injury”). If all of the contingencies occur at some point in the future, Ms. Prosser would be free to mount a challenge based on a concrete injury at that time.⁵

As noted above, two courts have agreed with the Secretary on lack of standing. As in this case, neither of these beneficiaries were financially liable for the denied coverage and there was no evidence that Novocure has subsequently required the plaintiffs to sign an Advance Beneficiary Notice to shift liability in the future. Both courts held that these same facts meant the beneficiaries suffered no injury in fact and dismissed the cases for lack of standing. *See Komatsu*, No. 8:20-cv-00280 (decision attached); *Pehoviack*, 2020 WL 4810961 (decision attached).

⁴ As Ms. Prosser asserted below, her claims for coverage were approved before subsequent ALJs. In the case on appeal, Ms. Prosser was denied for coverage for claims on January 16, 2018, February 16, 2018, March 16, 2018, and April 16, 2018. AR 4310–15. In the two ALJ decisions covering claims on May 16, 2018, June 16, 2018, July 16, 2018, August 16, 2018, September 16, 2018, and October 16, 2018, she received favorable decisions, granting coverage for these dates. AR 4238–52, 4254–62. These facts highlight how speculative it is that she will receive future denials if she continues to be prescribed TTFT.

⁵ Moreover, because the supplier bears the burden of non-coverage in the absence of an Advance Beneficiary Notice, a supplier accepting assignment would have standing to present a court challenge so the issue will not evade review. *See* 42 U.S.C. § 1395ff (b)(1)(C); *Cal. Clinical Lab. Assn. v. Secretary of HHS*, 104 F.Supp.3d 66, 81 (D.D.C. 2015). The beneficiary here, however, has suffered no injury and is simply the wrong plaintiff to bring this case due to her lack of standing.

B. No harm can be traced to the challenged conduct of the Secretary that could likely be redressed by a favorable decision

The Secretary maintains that there has been no injury. Even if this court were to find that Ms. Prosser's *potential future* liability for the *potential* denial of her *future* TTFT claims were an injury in fact, that injury would be traced to Novocure, not the Secretary.

The second element of standing requires that the injury be fairly traced to “the challenged action of the defendant,” and cannot be the result of “independent action of some third party not before the court.” *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41–42 (1976). Novocure has discretion whether to require Ms. Prosser to sign an Advanced Beneficiary notice and later bill her for treatment. *See Linda R.S. v. Richard D.*, 410 U.S. 614, 618–19 (1973) (holding that plaintiff lacked standing because there was no nexus between her failure to secure child support payments and the state's failure to enforce its child support statute); *Segovia v. United States*, 880 F.3d 384, 388–89 (7th Cir. 2018), *cert. denied* 139 S.Ct. 320 (2018) (finding harm could not be traced to federal government where non-party state had discretion to remedy harm without interference from federal government). As such, Novocure's discretionary action, not the Secretary's denial, would have caused the harm.

Lastly, Ms. Prosser cannot meet the third element required for standing—that a favorable decision could redress any alleged harm—because reversing the Secretary's coverage decision will have no effect on Ms. Prosser's liability or her past receipt of TTFT. The requirement that an injury be redressable by the court “tends to assure that the legal questions presented to the court will be resolved, not in the rarified atmosphere of a debating society, but in a concrete factual context conducive to a realistic appreciation of the consequences of judicial action.” *Valley Forge Christian Coll. v. Am. United for Separation of Church and State*, 454 U.S. 464, 472 (1982). A reversal of the Secretary's decision would change nothing—Ms. Prosser has already received

TTFT for dates at issue and she still would not be liable for the costs of the treatment. *See S.E. Lake View Neighbors v. Dep't of Hous. & Urban Dev.*, 685 F.2d 1027, 1037 (7th Cir. 1982) (finding any relief “valueless” because building already constructed).

VI. Conclusion

For the reasons set forth above, the Secretary respectfully requests this court grant summary judgment in his favor, finding that the Plaintiff lacks standing to pursue this action.

Dated at Milwaukee, Wisconsin this 8th day of October, 2020.

Respectfully submitted,

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